Exhibit 14

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456 Civil Action No. 01-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris

MERITS REPORT AND DECLARATION OF FIONA SCOTT MORTON, PH.D.

March 22, 2006

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LIST OF EXHIBITS

I. INTRODUCTION

A. Qualifications

1. My name is Fiona Scott Morton, and I am a Professor of Economics and Strategy at the Yale School of Management. After receiving a B.A. from Yale College and a Ph.D. from MIT, both in Economics, I taught at the Stanford University Graduate School of Business and the University of Chicago Graduate School of Business.

2. My primary expertise is in the study of firms, markets, and competition. I have undertaken research in a variety of industries, including pharmaceuticals, merchant shipping, wineries, funeral homes, e-commerce, automobile retailing, and magazines. In the pharmaceuticals industry, I have, or am, conducting research into competition, generic entry, and effects of procurement policies for pharmaceuticals for Medicaid and Medicare. My research has been widely disseminated through top peer-reviewed journals and research seminars and conferences to which I have been frequently invited.

3. I serve in an editing role for journals in the field of Industrial Organization, and have won several prestigious research grants from the National Science Foundation. In 2005–2006, I am the Adam Smith Visiting Fellow at the University of Edinburgh Economics Department in Scotland. My professional experience is described in my curriculum vitae, which is attached as Exhibit 1. I prepared an expert tutorial in this matter with Dr. Gregory Bell entitled, "An Orientation to the Acquisition of and Reimbursement for Prescription Drugs," submitted on December 3, 2004.

B. Overview of pharmaceutical industry

4. There are three parties in the pharmaceutical industry who are central to this case: manufacturers, providers, and payors. Manufacturers sell prescription drugs to wholesalers and various types of providers, who in this matter are primarily physicians, but may otherwise include pharmacies, hospitals, and other classes of trade. Providers then dispense drugs to patients and receive payments (often called "reimbursement") from the federal government through Part B of the Medicare

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program and/or third-party payors ("TPPs"), such as insurance companies and self-insured employers.

5. For the physician-administered drugs ("PADs") in this case, manufacturers usually sell the drugs to wholesalers or directly to physicians. Manufacturers may seek to charge different prices for different classes of trade (e.g., hospitals generally pay less than doctors, pharmacies, or wholesalers), and there is considerable variation in prices within classes of trade—not everyone pays the same price. Patients may share in the cost of drugs by making flat co-payments (e.g., $10 per prescription) or coinsurance (e.g., 5 percent of the physician's charge). Payors' reimbursements are often made at a percentage of the average wholesale price ("AWP"), which is reported by third-party price publications.

6. While this report is focused on PADs, it sometimes makes useful comparisons to self-administered drugs ("SADs"). Manufacturers of SADs sell the drugs to wholesalers, retail outlets, or the mail-order operations of pharmacy benefits managers ("PBMs"). Physicians do not take ownership of the drugs, though they continue to make the prescribing decision. The patient purchases the drug at the retail drugstore or receives it in the mail from the PBM. The drugstore is then reimbursed for the drug by the insurance company or PBM, which often acts as the middleman. The PBM is in turn reimbursed for the drug by the TPP. Government and third-party payors who reimburse for PADs generally have extensive experience with SADs.

C. Plaintiffs' theory

7. I understand that Plaintiffs filed their original complaint in this matter on July 16, 2002, although it has since been amended several times.[1] Judge Saris denied certification of a class for SADs,[2] but certified three classes for PADs:[3] a

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[1] Third Amended Master Consolidated Class Action Complaint, October 17, 2005 ("Third Amended Complaint").

[2] Judge Saris, Memorandum and Order Re: Motion for Class Certification, August 16, 2005, pp. 87–88.

nationwide class of Medicare Part B beneficiaries who paid co-payments based on AWP ("Class 1"), a Massachusetts class of TPPs who offered supplemental ("Medigap") insurance for PADs under Medicare Part B and paid based on AWP ("Class 2"), and a Massachusetts class of TPPs and consumers who paid for PADs based on contracts expressly using AWP outside of the Medicare context ("Class 3").

8. Plaintiffs allege that pharmaceutical manufacturers committed fraud by causing the publication of AWPs that did not have a predictable relationship to the drugs' average sale prices ("ASPs") and that payors could not mitigate the alleged fraud because the "spreads"[4] between AWP and ASP were not sufficiently transparent. Plaintiffs' expert Dr. Hartman contends that any subject drug whose "spread" exceeded 30 percent should result in liability.[5] More specifically, Plaintiffs allege the following:

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[3] Judge Saris, Consolidated Order Re: Motion for Class Certification, January 30, 2006 ("Class Certification Order"). Excluded from Class 1 are those who made flat co-payments, those who were or had the right to be fully reimbursed for co-payments, and residents of Alabama, Alaska, Georgia, Iowa, Kentucky, Louisiana, Mississippi, Montana, and Virginia (p. 2). Also excluded from Class 1 are persons who made co-payments for drugs manufactured by Schering Plough Group (p. 3). Excluded from Class 3 are payments or reimbursements for generic drugs based on MAC and not AWP (p. 6).

[4] Dr. Hartman uses several inconsistent definitions of the "spread" on drug purchases: (1) a spread on an individual purchase transaction calculated as the difference between AWP and actual acquisition cost (AAC); (2) a "spread" calculated as the difference between AWP and the average sale price (ASP), which does not reflect an actual market transaction; and (3) a "spread" calculated as the difference between AWP and an estimated average allowed amount for Medicare Part B or private payors (i.e., various percentages of AWP). His liability assessment uses the AWP-ASP definition, while his damages calculations use the allowed amount-ASP definition. See Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, September 3, 2004 ("Hartman Declaration of Sept. 3, 2004"), ¶ 8; Raymond S. Hartman, Declaration of Raymond S. Hartman in Support of Plaintiffs' Claims of Liability and Calculation of Damages, December 15, 2005 ("Hartman Liability Report"), ¶¶ 56, 63–65. Note that Dr. Hartman also uses the acronym "AAC" to mean both "actual acquisition cost" and "average acquisition cost" (Hartman Declaration of Sept. 3, 2004, ¶ 10 (b)), although I use it to mean "actual acquisition cost" in my report.

[5] Hartman Liability Report, ¶ 59 (e).

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1. **Payors expected AWP to exceed ASP by a reasonably predictable amount and that AWP would "signal" the AAC or ASP[6]**
2. **If the "spread" between AWP and ASP exceeded that predictable amount, payors were deceived[7]**
3. **Payors expected the "spread" for each drug to fall within the same predictable range[8]**
4. **Payors expected single-source drug "spreads" to be unchanged after the onset of therapeutic competition and generic competition[9]**
5. **Payors read particular government reports and interpreted the data they contain to form these expectations about "spreads"[10]**
6. **Payors were unaware of the vast variation in "spreads," rendering ASPs non-transparent and AWPs "inflated"[11]**
7. **The only reason for large "spreads" was that manufacturers wanted to move market share[12]**
8. **Moving market share necessitated deceiving payors about the size of the spread[13]**

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[6] Hartman Declaration of Sept. 3, 2004, Attachment D: ¶ 3; Rebuttal Declaration of Raymond S. Hartman in Support of Plaintiffs' Motion for Class Certification, December 16, 2004 ("Hartman Declaration of Dec. 16, 2004"), ¶ 3 (b).

[7] Hartman Declaration of Sept. 3, 2004, ¶ 10 (b).

[8] Hartman Declaration of Sept. 3, 2004, ¶¶ 28–33; Hartman Declaration of Dec. 16, 2004, ¶ 45 ("In the but-for world, AWP will shift, but the payors will remain at the same position on the bell-shaped frequency curve."); Hartman Liability Report, ¶¶ 22 , 28, and Figures 1.A–1.C (representing each payor as one point); Deposition of Raymond S. Hartman, February 27–March 1, 2006 ("Hartman Deposition"), pp. 1206–1207.

[9] Hartman Liability Report, ¶ 22.

[10] Hartman Declaration of Sept. 3, 2004, Attachment D: ¶¶ 21–25; Hartman Declaration of Dec. 16, 2004, fn. 13; Hartman Liability Report, ¶ 22.

[11] Hartman Declaration of Sept. 3, 2004, Executive Summary; Hartman Declaration of Dec. 16, 2004, ¶ 3 (c); Hartman Liability Report, ¶15.

[12] Third Amended Complaint, ¶ 6; Hartman Declaration of Sept. 3, 2004, ¶ 8; Hartman Declaration of Dec. 16, 2004, ¶ 3 (e); Hartman Liability Report, ¶¶ 15 and 22 (a); Hartman Deposition, pp. 1141–1143.

[13] Third Amended Complaint, ¶¶ 6–7; Hartman Declaration of Sept. 3, 2004, Attachment C: ¶ 35; Hartman Declaration of Dec. 16, 2004, ¶ 3 (e); Hartman Liability Report, ¶ 15.

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9. By administering drugs with larger spreads, providers put profit motives ahead of patient welfare[14]

10. If "spreads" were more transparent, payors would pay less for physician-administered drugs[15]

D. Scope of assignment

9. I have been asked by counsel for the Defendant pharmaceutical manufacturers to respond to Plaintiffs' allegations (which are summarized above) and examine the following specific issues:

- Are the arguments in the complaint and those put forth by Plaintiffs' experts Drs. Hartman and Rosenthal valid and reliable from the standpoint of economic theory?
- Are there valid and reliable economic explanations for the alleged conduct at issue?
- Would class members be better off in the but-for world that Plaintiffs suggest would have obtained if not for the alleged conduct?

E. Materials relied upon

10. In preparing my report, I have relied upon the materials cited in the report and those listed in Exhibit 2. I understand that discovery in this matter is not complete, and I reserve the right to revise or supplement my opinions, as appropriate.

F. Organization of my report

11. The next section of my report summarizes my opinions in this matter. The third section examines why Plaintiffs' theory that payors expect a predictable "spread" is implausible: it is illogical, explicitly contradicted by payors, contrary to principles of economic competition, and does not constitute an economic model of payors. Section four reviews the evidence that payors were not deceived by large

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[14] Hartman Declaration of Sept. 3, 2004, ¶ 10 d); Hartman Declaration of Dec. 16, 2004, ¶ 16 (h); Hartman Liability Report, ¶ 35, Attachment K: ¶ 5 (a). See, also, Third Amended Complaint, ¶¶ 5–6.

[15] Hartman Declaration of Dec. 16, 2004, ¶ 15 (f) , fn. 87; Hartman Liability Report, ¶ 15.

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"spreads"[16] and, in fact, purposefully used large "spreads" to encourage a shift in care out of hospitals, cross-subsidize other inadequately reimbursed services, ensure provider participation, encourage the use of generic drugs, and achieve other objectives. The fifth section examines why it is legitimate for there not to be a predictable relationship between a benchmark price and transaction prices. Section six examines why it is legitimate for a seller to keep constant or raise the benchmark price when average sale prices decline. The seventh section summarizes why the Plaintiffs' but-for world is not only implausible and would not save them any money, but would harm consumers.

II. Summary of Opinions

12. Plaintiffs' liability theory is fundamentally flawed and unreliable for several reasons.

A. Plaintiffs have not demonstrated that payors were deceived

1. Plaintiffs' analysis of liability ignores all evidence of individual payors' knowledge of spreads

13. While one of the cornerstones of Plaintiffs' liability theory is that payors were deceived about the magnitude of spreads, they fail to make this fundamental determination. Instead, Plaintiffs and their experts merely assume that payors were deceived. The public record of Medicare policymaking and testimony from third-party payors in this matter clearly refutes three fundamental assumptions in Plaintiffs' analysis and establishes that both public and private payors were generally (1) aware of spreads, (2) aware that spreads could be very large for some drugs, and (3) aware that spreads could be much larger for drugs facing therapeutic or generic competition than for single-source drugs.[17]

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[16] By "large spreads", I refer to spreads comparable to or larger than Dr. Hartman's 30 percent liability threshold. Dr. Hartman speaks of "mega-spreads" as reflecting reimbursement rates "which were in many cases 50%-1000% above the actual provider acquisition costs"; see Hartman Liability Report, ¶ 15.

[17] See sections III.A, III.C–III.E., and IV.

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14. Drs. Hartman and Rosenthal contend that payors informed their expectations during the class period using publicly-available materials, such as the numerous reports on pharmaceuticals since the 1980s by the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("DHHS") and other governmental bodies. These reports provide information on drug discounts and spreads for single-source and multi-source physician-administered and self-administered drugs. However, Dr. Hartman focuses only on selected averages for single-source innovator drugs gleaned from only one government report of 13 chemotherapy drugs administered in 5 physician practices in New York State, while turning a blind eye to evidence that would contradict his theory. He does not explain why payors would have also chosen such an unrepresentative sample of the available information.[18] Dr. Hartman's methodology is scientifically unreliable and deceptive.

15. Many private payors also learned about the relationship between AWP and acquisition costs as a result of their development of business units that purchased drugs directly from manufacturers—for example, through staff model health maintenance organizations ("HMOs"), specialty pharmacy operations, and mail order operations.[19] Among these knowledgeable entities are some of the largest commercial health plans in Massachusetts and the nation. These payors would likely be aware that spreads routinely increased with therapeutic competition and would build their knowledge into their expectations.

16. Further, Medicare Part B and many private payors used the spread on drugs to pay providers to participate in their networks, encourage a shift in care from the hospital to the doctors' office setting, promote the use of generic drugs, and cross-subsidize other inadequately reimbursed drugs, drug administration, and practice expenses.[20] Payors could easily observe whether offering a particular fee schedule was

[18] See section III.A.1.

[19] See section IV.B.1.

[20] See section IV.D.

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successful, because providers would refuse to participate if overall reimbursement levels were insufficient (after which normal market dynamics would compel payors to adjust reimbursement rates accordingly). Payors could also see, for example, whether they reimburse more for care performed in doctors' offices than in hospitals. These payors clearly could not be deceived by large spreads. In fact, they used spreads to achieve their reimbursement objectives.

2. Payors did not expect there to be a reasonably predictable relationship between AWP and providers' acquisition costs

17. Another cornerstone of Plaintiffs' liability theory is that payors had to and did use AWP as a signal for providers' acquisition costs. In particular, Plaintiffs contend that payors expected AWP to have a "reasonably predictable relationship" to providers' acquisition costs.

18. Dr. Hartman states that publicly available information—such as government reports and newspaper articles—informed payors' expectations of the "spread." However, he overlooks the fact that payors who read these publications would also have been aware of the reports' conclusions: AWP did not bear a consistent or predictable relationship to providers' acquisition costs. No reasonable industry participant would assume that a benchmark such as AWP with so much "noise" could be a reliable "signal" of acquisition costs.[21]

B. Plaintiffs' theory of expectations is not how payors set reimbursement rates and provides no basis for a liability analysis

1. Payors themselves discredit Plaintiffs' "expectations" theory

19. Plaintiffs' liability analysis is predicated on the unsupported assumption that payors set reimbursement rates based on their expectations of "spreads." Medicare policymaking and testimony from third-party payors in this matter contradict Plaintiffs' assumption.[22] Medicare policymakers and government agencies (such as the General Accounting Office ("GAO"), Medicare Payment Advisory Commission

[21] See section III.

[22] See section III.C.

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("MedPAC"), and OIG) conducted numerous studies of the relationship between AWP and acquisition costs; they publicly acknowledged the existence of large spreads and Medicare Part B's use of them to cross-subsidize drug administration and other inadequately-reimbursed physician practice expenses. Even though it had the ability to do so, Medicare did not adjust reimbursement rates to eliminate spreads. Instead, Congress repeatedly reaffirmed that the Medicare program should not reimburse at providers' acquisition costs. Nor did third-party payors rely on expectations of "spreads"; they relied on negotiations with providers to determine competitive reimbursement rates.

20. Most private payors who testified in this matter did not use acquisition costs in setting reimbursement rates and would not have changed reimbursements if they had more information on spreads.[23] Clearly, expectations of spreads have no impact on the welfare of either public or private payors, as payors simply did not use spreads in setting reimbursement rates. Thus, there is absolutely no foundation for Plaintiffs' expectations theory in analyzing liability: it does not provide any insight into how Medicare or private payors set reimbursement rates.

2. Dr. Hartman's "yardstick" does not measure payors' expectations

21. Dr. Hartman alleges that an AWP fraud occurred within each Defendant and drug, and asserts that payors had expectations about providers' drug acquisition costs. Drs. Hartman and Rosenthal contend that payors informed these expectations using a variety of publicly-available reports, which contained information on single-source and multi-source drugs. However, Dr. Hartman proposes a single "yardstick" to represent these purported expectations—that would be applied to each and every drug—by cherry-picking averages of only single-source innovator drugs gleaned from only one government report of 13 chemotherapy drugs administered in 5 physician practices in New York State. Many of the same reports he identified also highlighted so-called "mega-spreads" and the differences in spreads for single-source branded and multi-source self-administered and

[23] See section III.C.5.

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physician-administered drugs. Dr. Hartman's "yardstick" is clearly arbitrary, scientifically unreliable, and deceptive.[24] Drs. Hartman and Rosenthal portray payors—who are generally very large, complex entities—as being extremely unsophisticated and unable to learn or remember well-known facts about the industry, which is not credible.[25]

3. Dr. Hartman's and Dr. Rosenthal's theory of slow formal institutionalization of new information is arbitrary and self-serving

22. Dr. Hartman suggests that payors were slow to formally institutionalize new information and did not "institutionally understand" the information on so-called "mega-spreads" in the 1992 OIG report until 2004 to 2006.[26] Apparently Dr. Hartman believes that payors understood information on *single-source* drug spreads immediately, for he contends that this 1992 report informed payors' expectations throughout the class period, which begins in 1991. These positions are clearly arbitrary and self-serving. Drs. Hartman and Rosenthal do not offer any support in the economic literature for such a paradoxical pattern of institutional learning. If payors truly thought providers' acquisition costs were so important for setting reimbursement rates, they would not have disregarded large spreads that in later periods Dr. Hartman describes as flabbergasting them.

4. Dr. Hartman misrepresents what is revealed by payors' actions

23. Notwithstanding payors' statements to the contrary, Dr. Hartman contends that Medicare statutes and private payors' negotiations reveal that payors expected there to be a predictable relationship between AWP and acquisition costs for reimbursement purposes.[27] However, from the standpoint of economic theory, the only fact revealed by a reimbursement rate (in a statute or private contract) is *price* both parties have agreed to use for reimbursement purposes; a reimbursement rate

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[24] See section III.A.1.

[25] See section IV.B.4.

[26] See section III.A.6.

[27] See section III.B.

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says nothing about payors' *preferences*, nor their expectations, for providers' acquisition costs. The expectation of each party regarding operating costs of the other party—if any—is an entirely different topic. It is conceivable that the negotiated result would not meet the expectations of either or both of the parties.

24. Dr. Hartman contends that when payors finally have sufficient information about providers' costs, their preferences are revealed in actions, such as re-setting the terms and rates of reimbursement. However, his analysis effectively defines these actions to include only complete abandonment of AWP. Any other type of action to change reimbursement methods or rates is disregarded in a clearly self-serving manner. Dr. Hartman's approach ignores numerous actions by payors that were clearly motivated by institutional knowledge.[28] This steady flow of modifications to reimbursement methods and formulas also demonstrates that PAD reimbursement was not "unimportant" to payors. Dr. Hartman's approach also ignores payors' conscious decisions not to change reimbursement methods despite awareness of so-called "mega-spreads." For example, Blue Cross Blue Shield of Massachusetts ("BCBSMA") decided not to switch to an ASP+6 percent reimbursement regime since it might lead physicians to withdraw from its provider network, rendering it unviable.[29] These flaws render Dr. Hartman's analysis biased and unreliable.

25. Dr. Hartman also fails to come to grips with the most fundamental purpose of payors' reimbursement to providers: regardless of the reimbursement benchmark used by payors, physicians would seek reimbursement rates that cover their practice expenses (e.g., insurance, rent, nursing staff salaries, supplies)—which by and large do not depend on AWP—and maintain an acceptable overall profit margin.[30]

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[28] These actions by payors, which I discuss in section III.B., included implementation of Least Cost Alternative programs, Maximum Allowable Cost (MAC) programs, Medicare policy changes in the wake of the *Barron's* "Hooked on Drugs" article, constant efforts to reform reimbursement by the Department of Health and Human Services (HHS) throughout the 1990s, and various changes in Medicare Part B statutory reimbursement rates to reduce program expenditures.

[29] See section III.B.

[30] See section IV.D.

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Medicare Part B policymakers publicly acknowledged the importance of paying providers enough in total to assure their participation in the program. When in several cases Medicare reduced overall drug reimbursement without increasing reimbursements for drug administration, many providers found it financially unviable to continue participating in the Part B program. Similarly, private payors testified in this matter that they negotiated on the overall bundle of drugs and services in the fee schedule. When providers objected to the fee schedule, private payors generally increased it across the board by a mutually agreeable percentage (rather than renegotiate the reimbursement for each item individually). Public and private payors' focus on overall payments to providers allowed there to be substantial variation in spreads across individual drugs, including possibly negative spreads. Dr. Hartman and Dr. Rosenthal focus on something that is unimportant to providers: the *percentage* spread on drugs. However, the dollar value of a spread can be very small even though the percentage spread is quite large.[31] What matters most is the overall *dollar* margin across drugs and services, which helps physicians cover their practice expenses and continue to provide services to patients.

C. Plaintiffs incorrectly assume that Medicare intended "spreads" to be "zero by statute"

26. While I am not in a position to provide a legal analysis of the proper interpretation of the Medicare statutes and regulations, it is clear to me that Dr. Hartman has failed to conduct even a rudimentary economic analysis to validate his assumptions. Dr. Hartman's assumptions are contrary to actions of Congress and government officials, which were readily observable.

1. Dr. Hartman's analysis apparently relies on a faulty economic interpretation of the Medicare regulations

27. Dr. Hartman suggests the but-for "spread" for the Medicare classes was "zero by statute" for nearly the entire class period based on his interpretation of two changes in regulatory language: (1) a change effective in 1992 that Part B drugs be paid at

[31] See, for example, section IV.D.5.

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the lesser of the Estimated Acquisition Cost (EAC) or AWP,[32] and (2) a 1998 change to pay at the lesser of the billed charge on the claim form or 95 percent of AWP.[33] Dr. Hartman's *assumption* that a but-for "spread" of zero percent is appropriate for the Medicare classes does not constitute an economic *analysis*, and he fails to support this assumption for several reasons. Dr. Hartman maintains that Medicare regulations intended EAC to equal AWP, although it stands to reason that policymakers would not have enacted the EAC provision if it were redundant to the AWP language. More importantly, Dr. Hartman apparently fails to come to grips with the fact that the EAC provisions in the regulations were not implemented and the Health Care Financing Administration ("HCFA") instructed carriers not to reimburse drugs based on EAC.[34] Dr. Hartman also incorrectly assumed that the actual *charge* on a Medicare claim form for reimbursement equals the provider's actual acquisition *cost* in the regulations,[35] although it is common knowledge in the industry that these terms differ. Dr. Hartman was asked by counsel to make the "zero by statute" assumption in his supplemental report.[36]

2. Congress and government officials confirm that Dr. Hartman's interpretation is wrong

28. Dr. Hartman did not examine the legislative or statutory history of Medicare Part B.[37] If he had done so, he would have found that HCFA chose to reimburse Medicare Part B drugs with spreads that were well above providers' acquisition

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[32] Hartman Declaration of Sept. 3, 2004, fn. 52; Hartman Liability Report, ¶ 19.

[33] Hartman Liability Report, ¶ 18.

[34] Letter from Frank J. Camozzi, Chief, Technical Issues Section, Division of Medicare, November 4, 1994, HHC015-1693–94 at HHC015-1693; Letter from Grant Steffen, MD, Blue Cross Blue Shield of North Dakota, Medicare, HHC908-1217–18, HHC014-0177; and Hartman Deposition, pp. 876–894, 914–919.

[35] Hartman Deposition, pp. 894–901.

[36] Hartman Deposition, pp. 843–844.

[37] Hartman Deposition, pp. 806–807, 923.

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costs and that Congress repeatedly chose not to eliminate providers' markups on drugs because they served essential purposes of the program.[38]

29. Further, Dr. Hartman admitted in deposition testimony that if Medicare Part B drugs were reimbursed at a zero percent "spread," providers would be paid at rates below the Medicare program's expectations.[39] Dr. Hartman also admitted that his supplemental report, which also assigns liability based on the "zero by statute" interpretation, is inconsistent with his analysis of liability;[40] he made the assumption on the instruction of counsel.[41]

D. Dr. Hartman's and Dr. Rosenthal's analyses are unreliable

1. Dr. Hartman's empirical observations do not constitute an economic model

30. Dr. Hartman's statement that "[t]he basis for my finding of causation and liability is empirical"[42] is not scientifically valid. In order to validate a theory empirically, an economist should first develop a plausible theory whose hypotheses can be tested, test the hypotheses using an economic model, and evaluate the sensitivity of results to underlying assumptions. Dr. Hartman fails to propose any valid research hypotheses (let alone testable hypotheses), fails to develop a plausible economic model, fails to conduct a valid empirical test of hypotheses using an economic model, and fails to consider the sensitivity of the results to his assumptions.

31. First, Dr. Hartman fails to propose a plausible theory of liability.[43] He has not articulated a theory of how payors incorporate information from publicly-available materials and their own experiences, form expectations, or set reimbursement rates.

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[38] See section IV.D.

[39] Hartman Deposition, pp. 1263–1265, describes how his Supplemental Report would assess Medicare damages even though the liability threshold had not been exceeded. The same flaw affects his original Liability Report, which also applied a 30 percent liability threshold and a 0 percent but-for spread for Medicare damages calculations.

[40] Hartman Deposition, pp. 661–662.

[41] Hartman Deposition, pp. 647–648.

[42] Hartman Liability Report, ¶ 56.

[43] See section III.

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Without an economic theory of how payors would normally behave, Dr. Hartman cannot systematically evaluate how payors could be deceived or defrauded as alleged by any information or action, or what reimbursement rates would be consistent with alleged deception or fraud. Also, the theory may help guide the selection of relevant variables for the economic model, which should encompass potential causal factors, confounding factors, and outcomes.

32. Second, Dr. Hartman fails to propose any research hypotheses associated with his conception of liability. A research hypothesis should clearly state the *expected* relationship, based on the theory, between two or more relevant variables. Without knowing the expected relationship, it would not be possible to construct a test of a hypothesis such as "firm X was behaving fraudulently in setting the AWP of drug Y at $Z." In order for such a hypothesis to be testable, at least one alternative hypothesis must be specified, such as "the setting of AWP of drug Y at $Z by firm X is consistent with normal competitive behavior." Without an alternative hypothesis (and an underlying economic theory to sort out the differences), one cannot empirically evaluate the causality theorized in a hypothesis and determine whether the evidence supports it or not.

33. Third, Dr. Hartman considers only one such potential factor in how payors set reimbursement rates: he assumes the (only) reason for spreads is to move market share. It is readily apparent that Dr. Hartman's model is incapable of evaluating the effects of any other economic factor on "spreads," such as the characteristics of specific drugs within a therapeutic class, market conditions for transactions between specific classes of payors and types of providers, information available to payors, or the dynamics of competition. Dr. Hartman's "model" fails to account for factors that determine list prices or transaction prices in a normal competitive environment.[44]

34. Fourth, Dr. Hartman has not performed a valid empirical test of his liability "theory." As I discuss above, Dr. Hartman has not developed the essential elements

[44] See sections III.D, V, and VI.

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(i.e., a plausible theory, testable research hypotheses, and economic model) necessary to conduct an empirical test of a specific theory. Put another way, one cannot precisely define what economic theory is being "tested" by Dr. Hartman's empirical observations. It is unclear how his "model" could be tested under a different set of economic conditions. In Dr. Hartman's "model," one cannot determine the degree to which (or the mechanism by which) a doubling of spreads would affect liability without first assuming his conclusion of a specific liability threshold. Nor could one use Dr. Hartman's empirical observations to determine the effect of payors' knowledge of spreads on liability—for any one of the three Classes or any specific Class member.

35. Dr. Hartman's theory of expectations has been contradicted by payors themselves,[45] thus it is unclear how it could serve as a legitimate basis for a liability analysis. Dr. Hartman has not presented an economic model that would produce a specific liability threshold, let alone the thresholds that he assumes as conclusions (30 percent or 0 percent). Dr. Hartman's liability "model" bears no relationship to how payors set reimbursement rates, and his empirical observations do not inform the issue of liability.

2. Dr. Hartman and Dr. Rosenthal assume their conclusions and have contradictory positions

36. Dr. Hartman was asked by counsel to *assume* liability and causation in his Affirmative and Rebuttal Declarations in Support of Class Certification, and uses the same methodology for examining liability and causation in his Liability Report.[46] Dr. Rosenthal was asked by counsel to *assume* that the allegations in the Third Amended Complaint were true[47] and that Dr. Hartman's liability analysis was correct.[48] Dr. Rosenthal did not perform any independent analysis of liability.[49]

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[45] See section III.C.1.

[46] Hartman Liability Report, ¶¶ 9–10.

[47] Deposition of Meredith Rosenthal, February 22–23, 2006 ("Rosenthal Deposition"), pp. 62–63.

[48] Rosenthal Deposition, pp. 61–62, 386–387.

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Nonetheless, both Drs. Hartman and Rosenthal contend they have made findings of liability.[50]

37. Drs. Hartman and Rosenthal have also used circular reasoning or relied on inconsistent positions at intermediate points in their analyses. While I discuss these issues throughout my report, I note several examples here:

38. Dr. Rosenthal contends that individual payors' opinions are not relevant[51] and self-reported surveys are unreliable,[52] but both Drs. Hartman and Rosenthal find it acceptable to rely upon the Dyckman survey of self-reported information to reach conclusions on third-party payors' reimbursement methods.[53]

39. Dr. Hartman contends that "a yardstick to define the expectations in the market should take advantage of as much information as is available,"[54] yet he chose to develop a "yardstick" based only on single-source drugs despite information in the same sources on multi-source spreads.[55] He later concludes that Medicare Part B multi-source drug "spreads" exceeded expectations reflected in his "yardstick," which is unrepresentative.

3. Dr. Hartman and Dr. Rosenthal did not empirically validate their hypotheses

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[49] Rosenthal Deposition, pp. 51–52. Dr. Rosenthal did not offer an opinion on what payors expected the difference between AWP and acquisition cost to be (p. 71), no opinion on the "market expectation" (pp. 48–50), no opinion on whether Dr. Hartman's 30 percent "bright line" liability threshold is reasonable (pp. 72–78), and no opinion on whether manufacturers had an intent to deceive (pp. 97–98).

[50] Hartman Liability Report, ¶ 3; Liability Report of Dr. Meredith Rosenthal, December 15, 2005 ("Rosenthal Liability Report"), pp. 1–2.

[51] Rosenthal Deposition, pp. 138–140.

[52] Rosenthal Deposition, pp. 181–183.

[53] Hartman Liability Report, ¶¶ 22 (c), 27, 28 (a), 30 (b), 45 (a), 65, and Attachment J.6: p. 2 (citing Medicare Payment Advisory Commission, Report to the Congress, Variation and Innovation in Medicare, June 2003, Table 9-2 (p. 166), which presents results of the Dyckman & Associates survey of health plans in 2002); Rosenthal Liability Report, ¶ 22, fn. 21 (citing "Health Plan Payment for Physician-Administered Drugs, a study conducted by Dyckman & Associates for the Medicare Payment Advisory Commission, August 2003"; p. 2 contains a description of the survey methodology).

[54] Hartman Deposition, pp. 704–706.

[55] Hartman Deposition, pp. 667–669, 726–732.

40. Drs. Hartman and Rosenthal did not derive their hypotheses of liability from any empirical analysis of actual payors in this matter. In fact, Dr. Rosenthal did not rely on any of the payor deposition testimony,[56] and Dr. Hartman did not conduct a systematic study of the testimony.[57] By the same token, Drs. Hartman and Rosenthal did not validate their theory of liability (i.e., that payors rely on expectations of "spreads" to set reimbursement rates) with any empirical analysis.[58] The fact that payor after payor refuted their most basic assertions[59] should have at least signaled the need for a careful reexamination of underlying assumptions that is a hallmark of sound principles of scientific analysis.

4. Dr. Hartman's and Dr. Rosenthal's analyses of liability are based on numerous unproven assumptions that are contrary to economic principles

41. Plaintiffs' analysis of liability relies on a number of unproven assumptions that are contradicted by basic economic principles and well-known aspects of competition in the industry. First, Plaintiffs assume that there is no legitimate reason not to have a predictable relationship between benchmark prices and transaction prices, ignoring the economic ramifications of patent protection for margins over the product lifecycle, the effects of constantly changing competitive conditions and advance of science, and the role of price concessions (that are variable and confidential) in promoting competition.[60]

42. Second, Plaintiffs assume that there are no legitimate reasons for manufacturers to keep constant or raise the benchmark price when the ASP declines, ignoring common purposes of benchmark prices (e.g., providing the flexibility to adjust prices for future contingencies, maintaining a premium product image, allowing payors to create margins for providers without affecting transactions prices).

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[56] Rosenthal Deposition, pp. 34–37.

[57] Hartman Deposition, pp. 686–687, 707–710.

[58] Hartman Deposition, pp. 795–796; Rosenthal Deposition, pp. 52–54.

[59] See section III.C.

[60] See section V.

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Plaintiffs do not consider that benchmark prices resemble the economic concept of a list price, which reflects a reference point that is rarely reduced.[61]

43. Third, Plaintiffs assume that Medicare and private payors would have implemented expectations-based reimbursement rates if there were more transparent pricing, payors would save money, and consumers would benefit. However, payors would not have implemented Plaintiffs' but-for world because it would likely increase the total costs of health care by driving care back into the hospital, and reduced competition in the but-for world would ultimately cause increased prices that would harm payors and consumers.[62]

5. Plaintiffs' liability "threshold" is arbitrary and cannot distinguish "fraud" from competition

44. Plaintiffs' analysis would have ascribed fraudulent motives to even the most vigorous competition if it resulted in large spreads. The fallacy in Plaintiffs' assumption is readily apparent when we consider that competition generally lowers total health care costs—for example, payors have for many years intentionally paid pharmacists a higher margin on generic drugs than brand drugs to encourage generic substitution in order to reduce total health care costs.

45. The arbitrary nature of Dr. Hartman's "yardsticks" stem from the fact that he has picked a handful of drugs that do not face competition (and for these drugs, an arbitrary and overly-selective set of "spreads") and compared them to drugs with competitors.[63] His design would measure "spreads" in a market but-for *competition from therapeutic substitutes*. He does not perform the comparison relevant to this matter, which is a measure of spreads in a market but-for *the alleged fraud*. Apparently Dr. Hartman has overlooked a lesson that payors have surely not forgotten: their experiences with SADs convincingly demonstrated that competition

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[61] See section VI.

[62] See section VII.

[63] See section III.

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causes price concessions,[64] which may cause increased spreads. Payors for these drugs—which were ruled out of the case—apparently did not suffer injury and damages.[65]

E. Plaintiffs' but-for world would not save payors money and would harm consumers

46. Plaintiffs' but-for world is not only implausible and unlikely to have occurred,[66] but it would not have saved payors money.[67] The implied reductions in payments to physicians would very likely cause the provision of office-based PADs to shift back into hospitals, raising payors' costs several fold. If Dr. Rosenthal's assertion that physicians have enough market power to earn excess profits were true, then physicians would also exercise that market power in the but-for world to gain higher drug administration fees to offset reductions in drug spreads.

47. Plaintiffs' assumption that payors need greater price transparency to make efficient reimbursement decisions is simply incorrect as a matter of economics. This oversight is also at the heart of why Plaintiffs' but-for world would harm consumers. It would destroy incentives for price competition among drug manufacturers, leading to higher provider reimbursements, higher insurance premiums, and higher prices paid by consumers of physician-administered drugs. The fallacy in Plaintiffs' assumption has been clearly articulated by the Federal

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[64] Deposition of John M. Killion (Senior Director, Ancillary Services, BCBSMA), January 6, 2006 ("Killion Deposition"), pp. 6, 122–129; Deposition of Eric Cannon (Director of Pharmacy Services, IHC Health Plans), September 13, 2004 ("Cannon Deposition"), pp. 7, 35–36. Discounts for generic drugs could be substantially larger than those for brand name drugs, as exemplified by Harvard Pilgrim Health Care's drug purchasing for its staff model HMO; see Deposition of James Kenney (Pharmacy operations manager, Harvard Pilgrim Health Care), September 20, 2004 ("Kenney Deposition"), pp. 6–7, 12–15.

[65] Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, February 9, 2005 ("Berndt Report"), ¶ 209.

[66] See section VII.A.

[67] See section VII.B.

Trade Commission and empirically demonstrated by experiences with Medicaid rebate rules.[68]

III. Plaintiffs' Theory that Payors Expect a Predictable "Spread" is Implausible

48. Plaintiffs have proposed a theory of payors' expectations that does not rely upon analysis of the actual expectations of any payor. The theory is not only illogical, but it is explicitly contradicted by payors' testimony in this matter. Plaintiffs' theory is also inconsistent with well-known principles of the economics of competition and features of the pharmaceutical industry.

A. Plaintiffs' expectations theory is illogical

1. Plaintiffs' theory has payors culling only group averages from studies of selected drugs to form specific expectations of a "spread" range for each and every drug

49. According to Dr. Hartman, payors form expectations using average "spreads" for groups of drugs studied in selected government reports.[69] Although these reports often reveal large "spreads" for individual drugs,[70, 71, 72] which vary and may include both single-source and multi-source drugs, Dr. Hartman would have payors

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[68] See section III.C.

[69] Hartman Declaration of Sept. 3, 2004, ¶¶ 28–29 and Attachment D: ¶ 24; Hartman Deposition, pp. 726–740. Although he identifies some information that is publicly available, Dr. Hartman does not describe how payors form expectations in his Liability Report or Deposition. However, he proposes a "yardstick" methodology to estimate but-for spreads; see Hartman Liability Report, ¶ 22.

[70] A 1992 OIG Report that studied 13 chemotherapy drugs (including some in this litigation) administered in New York State, cited by Dr. Hartman, actually reported manufacturer discounts off AWP of 20 percent to 83 percent (or spreads of 25 percent to 488 percent) for single-source and multi-source drugs; see OIG, *Physicians' Costs for Chemotherapy Drugs*, A-02-91-01049, November 1992 ("1992 OIG Report"), Appendix III. This range is much larger than that reported by Dr. Hartman; see Hartman Liability Report, ¶ 22.

[71] In a 2001 report, the General Accounting Office (GAO) found that Medicare Part B drugs were widely available to providers at 13 to 86 percent below AWP (or spreads of 15 percent to 614 percent); see the comments of Dr. Joan Sokolovsky in MedPAC, Payment Method for Medicare-Covered Outpatient Drugs, Public Meeting transcript, March 21, 2003, p. 2.

[72] Dr. Hartman also relies on a 2002 study of private health plans by Dyckman & Associates study, which found PAD reimbursements to vary from 85 percent to 115 percent of AWP; see Hartman Declaration of Sept. 3, 2004, Attachment D: ¶ 30.

disregard the full extent of variation in spreads and take only the narrower range of average "spreads" across groups of single-source drugs as informative.[73] Dr. Hartman offers no theory to explain how payors were able to reject information on multi-source drug spreads as unrepresentative or false,[74] and his position is fundamentally inconsistent with Plaintiffs' assumption that payors want as much information on spreads as possible.

50. Dr. Hartman dismisses as anecdotal and not "systematic [and] transparent" the information on multi-source drugs (for example, in OIG reports and the *Barron's* article),[75] but performs no statistical analysis of the representativeness of the information he hand-picks from OIG reports, his list of 29 comparator drugs, or the 3 drugs he ultimately used in developing his "liability threshold."[76]

51. One of the "notable examples" of government reports cited by Dr. Hartman as used by payors to form expectations of the spread was a 1992 OIG report that covered 13 chemotherapy drugs administered in 5 physician practices in New York State. In fact, he apparently relies only on 4 single-source physician-administered drug "spreads" he calculated from this one OIG report.[77] However, even the OIG and the HCFA express reservations about the report's small study sample.[78]

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[73] Hartman Liability Report, ¶ 58; Hartman Deposition, pp. 726–740.

[74] When asked in deposition whether payors would interpret reported information on multi-source drugs differently from that of single-source drugs, Dr. Hartman does suggest that payors were slow to respond and incorporate information into their expectations (Hartman Deposition, pp. 730–733); however, he offers no theory or evidence that payors' learning process differs for single-source and multi-source drugs.

[75] Hartman Deposition, pp. 849–852. See, also, 1992 OIG Report; OIG, *Excessive Medicare Payments for Prescription Drugs*, OEI-03-97-00290, December 1997 ("1997 OIG Report"), p. ii, Appendix B. See, also, Hartman Liability Report, ¶ 22 (b), (c); Hartman Declaration of Dec. 16, 2004; and Alpert, Bill, "Hooked on Drugs: Why do Insurers Pay Such Outrageous Prices for Pharmaceuticals," *Barron's*, June 10, 1996, pp. 15–16, 18 ("Hooked on Drugs, 1996").

[76] Hartman Liability Report, ¶¶ 22 and 59, and Table 3. See, also, 1992 OIG Report; 1997 OIG Report.

[77] Hartman Liability Report, ¶ 22 (b) (citing ¶ 30 (a) of his Sept. 3, 2004 declaration, which makes reference to Attachment D: ¶ 22, which states: "The OIG found that physician invoice costs were consistently 20% below the published AWP for brand-name drugs without a generic available (single-source drugs.)"). See, also, 1992 OIG Report, Appendix III (which displays 4 single-source drugs with discounts from brand name manufacturers of 20 percent off AWP: Bleomycin, Carboplatin, Etoposide, and Mitomycin). Dr. Hartman claims that the 1992 OIG Report "was broadened in 2001 by the

2. Plaintiffs' theory has each payor forming the same expectation of the "spread" range for each and every drug

52. According to Plaintiffs, each payor also applied the same selective average range of expectation of "spreads" to each and every drug they reimbursed. A single payor developed an expectation within the narrow range in the reported averages: this, the payor then applied across all drugs. If this were true, payors did not consider the economic conditions facing any drug or therapeutic class in forming expectations of "spreads" for specific drugs. This is illogical, especially in light of the information *in the same reports*—that, according to Dr. Hartman, were used by payors—clearly demonstrating the variation in "spreads" across drugs. Plaintiffs' assumption is also contradicted by the record in this matter, as I discuss below.

3. Plaintiffs' theory has payors forming expectations that are independent of market conditions

53. Plaintiffs' theory would not allow payors to acknowledge variation in spreads or analyze the potential sources of that variation. Because Plaintiffs assume that payors regard an average "spread" from a few drugs as indicative of all spreads at all times, in Plaintiffs' but-for world, payors' expectations would be independent of every economic factor: characteristics of the market (such as competition), characteristics of the drug, and characteristics of the buyer.

4. Plaintiffs' theory characterizes payors' expectations as unchanging over the product lifecycle

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American Society of Clinical Oncology (ASCO) to more single-source physician-administered drugs" (Hartman Liability Report, 22 ¶ (b)), although it uses the data from the 1992 OIG Report.

[78] "Our review was limited to a small judgmental sample of patients and physicians in New York State" (1992 OIG Report, p. 1). In response to the OIG recommendation that "HCFA should define reimbursement policy to encourage physicians to purchase drugs utilizing the most economical means available in the marketplace", HCFA responded: "HCFA does not concur with the recommendation. We are not prepared to agree that HCFA should reimburse physicians at the lowest price available in the marketplace without further evidence that a substantial number of physicians have access to that price"; see page 3 of the Letter from William Toby, Jr. Acting Administrator, HCFA, to the Inspector General, July 20, 1992, which is attached to 1992 OIG Report.

54. Plaintiffs endow every payor with remarkably simplistic expectations: its expectation of the spread does not vary with the drug, therapeutic class, buyer characteristics, or the market. In particular, Plaintiffs' theory is that payors form expectations based on a brand name drug's "spread" while it is a single-source drug, and continue to expect exactly the same "spread" once the drug encounters therapeutic or generic competition (without ever learning that the "spread" may differ over the product lifecycle).[79] Plaintiffs' theory does not incorporate even the most rudimentary characteristics of economic markets or the pharmaceutical industry, not even those characteristics acknowledged by third-party payor deponents in this matter.[80]

5. Plaintiffs' theory would require manufacturers to know payors' expectations

55. According to Plaintiffs, manufacturers also have to establish prices that fall within an acceptable range of payors' expectations of "spreads" to avoid fraud. However, payors' expectations are not published or communicated to manufacturers in any formal manner; nor are manufacturers privy to negotiations and other communications between payors and providers. Given the lack of reliable information on payors' expectations, Plaintiffs do not explain how manufacturers could avoid the alleged fraud.

56. More specifically, Plaintiffs' theory would require generic manufacturers to be aware of payors' expectations to avoid fraud. This would be a remarkably difficult feat because, while parties knowledgeable about the industry know there would be significant discounting upon generic entry, no one can accurately predict the intensity of price competition and thus expectations would be expected to vary a great deal. Price competition would depend on many factors, including how many

[79] Hartman Liability Report, ¶ 22.

[80] For example, Harvard Pilgrim Health Care purchased drugs directly from manufacturers for its staff model HMOs in Massachusetts, thereby learning that single-source spreads and multi-source drug discounts were substantial and differed. See Kenney Deposition (Harvard Pilgrim Health Care), pp. 11–15. I discuss other characteristics of pharmaceutical markets in section III.C.–III.E.

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generic firms entered, on what dates, and with what capacities. Again, Plaintiffs' theory does not incorporate well-known aspects of competition in the pharmaceutical industry.

6. Plaintiffs' theory of slow formal institutionalization of new information is arbitrary and self-serving

57. When asked how payors could not have been aware of the existence of so-called "mega-spreads" from the very same government reports that he cites, Dr. Hartman suggests that payors were slow to formally institutionalize such new information, although he provides no economic analysis to support any theory of learning. Dr. Hartman suggests that payors did not "institutionally understand" such information on multi-source "spreads" in the 1992 OIG report until around 2004 to 2006.[81] However, apparently Dr. Hartman believes that payors understood the information on smaller *single-source* drug "spreads" immediately, for he contends that this 1992 report informed payors' expectations throughout the class period,[82] which begins in 1991. These positions are clearly arbitrary and self-serving. Drs. Hartman and Rosenthal do not offer any support in the economic literature for such a paradoxical pattern of institutional learning, and if payors truly thought providers' acquisition costs were important for setting reimbursement rates, they would not disregard large "spreads" that in later periods Dr. Hartman describes as flabbergasting them.[83]

7. Dr. Hartman applies a fixed "liability threshold" to changing expectations

58. In deposition testimony, Dr. Hartman acknowledged that payors' expectations of "spreads" have changed over the past 15 years.[84] However, he applies an unchanging "liability threshold" throughout his liability analysis. Similarly, Dr.

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[81] Hartman Deposition, pp. 764–768, 840–841. Dr. Hartman refers to the 1992 OIG Report.

[82] Hartman Deposition, pp. 726–727, 764–766.

[83] Hartman Deposition, p. 770. Dr. Hartman adopts this term from a comment made by an AdvancePCS executive in a telephone interview, excerpts of which are reported in "AdvancePCS Views its Specialty Rx as Complementary to Caremark's Approach," *Specialty Pharmacy News*, Vol. 1, No. 2, March 2004, pp. 1–3.

[84] Hartman Deposition, pp. 784–785.

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Hartman applies an unchanging but-for "spread" in his damages analysis. These flaws are symptomatic of the inability of Dr. Hartman's methodology to incorporate any increased knowledge or meaningful variation in the economic factors that may influence pricing or expectations in the pharmaceutical industry.

B. Dr. Hartman's "revealed preferences" theory is biased and unreliable

59. Notwithstanding payors' statements to the contrary,[85] Dr. Hartman contends that Medicare statutes and private payors' negotiations reveal that payors expected there to be a predictable relationship between AWP and acquisition costs for reimbursement purposes. However, from the standpoint of economic theory, the only fact revealed by a reimbursement rate (in a statute or private contract) is the *price* both parties have agreed to use for reimbursement purposes; a reimbursement rate says nothing about payors' *preferences*, nor their expectations about providers' acquisition costs. This transaction price is the outcome of a negotiation between payors and providers in which payors try to bargain down providers to the lowest rate the providers are willing to accept, while providers try to extract the highest rate they can from payors. The expectation each party regarding operating costs of the other party—if any—is an entirely different topic. It is conceivable that the negotiated result would not meet the expectations of one or both of the parties. Dr. Hartman does not provide a testable hypothesis as to how reimbursement rates could reveal any preferences of providers.

60. The reimbursement rates that physicians seek are driven by their practice expenses, which, by and large, do not depend on AWP—insurance, rent, nursing staff salaries, supplies, etc. Regardless of the reimbursement benchmark used by payors, physicians would seek to cover practice expenses and maintain an acceptable profit margin. Medicare Part B policymakers publicly acknowledged the importance of paying providers enough in total to assure their participation in the program. In several cases where Medicare reduced overall drug reimbursement without increasing reimbursements for drug administration, they observed that many

[85] See section III.C.1.

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providers found it financially unviable to continue participating in the Part B program.[86] Similarly, private payors testified in this matter that they negotiated on the overall bundle of drugs and services in the fee schedule, and when providers objected to the fee schedule payors increased it across the board by a mutually agreeable percentage (rather than renegotiating the reimbursement for each item individually).[87] Payors' focus on overall payments to providers allowed there to be substantial variation in "spreads" across individual drugs.

61. Dr. Hartman contends that when payors have sufficient information, their preferences are revealed in actions, such as setting the terms and rates of reimbursement.[88] However, his "revealed preferences" approach is unable to detect most types of reimbursement policy change except complete abandonment of AWP. In fact, Dr. Hartman's approach is biased and unreliable for several reasons.

62. First, Dr. Hartman's approach ignores numerous actions by payors that were clearly motivated by institutional knowledge, including implementation of Least Cost Alternative programs, implementation of Maximum Allowable Cost ("MAC") programs, Medicare policy changes in the wake of the *Barron's* "Hooked on Drugs" article, constant efforts to reform reimbursement by the Department of Health and Human Services ("HHS") throughout the 1990s, and various changes in Medicare Part B statutory reimbursement rates to reduce program expenditures. These numerous reforms also demonstrate that PAD reimbursement was not "unimportant" to payors.[89]

63. Second, Dr. Hartman's approach ignores payors' conscious decisions not to change reimbursement methods despite awareness of so-called "mega-spreads." For example, Blue Cross Blue Shield of Massachusetts ("BCBSMA") decided not to switch to an ASP+6 percent reimbursement regime since it might lead physicians to

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[86] See section III.C.4, which provides examples of Medicare changes to reimbursement for chemotherapy drugs and intravenous immunoglobulin.

[87] See section III.C.4.

[88] Hartman Deposition, pp. 823–824.

[89] See section IV.B.5.

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withdraw from its provider network, rendering it unviable.[90] Despite testimony that BCBSMA consciously chose not to switch to an ASP-based reimbursement system for PADs, Dr. Hartman concludes that payors were stymied by "various institutional reasons and information technology reasons you are locked into a certain reimbursement system that was based on other expectations."[91]

64. Third, since Dr. Hartman's approach is only designed to detect changes, it cannot account for payors' purposeful and ongoing use of spreads to provide incentives to physicians, such as encouraging a shift in care out of hospitals and ensuring physicians' participation in provider networks.[92]

65. Fourth, Dr. Hartman admits that expectations differ "quite a bit" from contract prices.[93] Thus, it is likely that what is revealed by contract reimbursement rates—if anything—is not very precise and, in any case, not accounted for in Dr. Hartman's comparisons of his liability threshold to actual "spreads."

C. Plaintiffs' expectations theory is explicitly contradicted by payors

1. Medicare and private payors did not expect there to be a predictable relationship between AWP and providers' acquisition cost

66. Dr. Hartman relies on a 1992 OIG report that covered 13 chemotherapy drugs, but does not report the key findings of that report, which payors would have known when forming their expectations: "AWP is not a reliable indicator of the cost of a drug to physicians"[94] and "[c]onsidering that we also found that there is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of physicians' acquisition cost, we do not feel that AWP provides a useful

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[90] Deposition of Michael T. Mulrey (Manager of provider reimbursement within the actuarial area, BCBSMA), January 5, 2006 ("Mulrey Deposition"), pp. 5, 65–73, 129–130. See, also, Hartman Deposition, pp. 828–834, and Hartman Deposition Ex. 35 ("Analysis of CMS Average Wholesale Price Reform," February 7, 2006, which is also marked as Mulrey Deposition Ex. 2): p. 12.

[91] Hartman Deposition, pp. 840–841.

[92] See section IV.D.

[93] Hartman Deposition, pp. 784–785.

[94] 1992 OIG Report, p. 2 (which includes a cover letter from William Toby, Jr., Acting Administrator, Health Care Financing Administration).

measure of the acquisition cost for a drug to physicians."[95] Dr. Hartman also ignores one of the key findings of the 1997 OIG report he references: AWPs "bear little or no resemblance to actual wholesale prices that are available to the physician and supplier communities."[96]

67. Dr. Hartman did not analyze the legislative or statutory history of Medicare Part B,[97] which would have revealed the fallacy of his expectations theory. In January 1998, the head of the HCFA wrote to Representative Stark that "while Medicare policy is to pay at the average wholesale price (AWP) for drugs, the prices reported by the commercial sources of this information do not accurately reflect the true wholesale price in the marketplace. We have been aware of this problem…"[98] In a 1999 report to Congress, the head of the Department of Health and Human Services concluded with "the OIG finding cited earlier in this report that, as an unregulated, suggested price, typically set by the manufacturer, the AWP bears no consistent or predictable relationship to the prices actually paid by physicians and suppliers to drug wholesalers in the marketplace."[99]

68. Dr. Hartman also ignores the testimony of private payors, some of whom either did not expect a predictable or consistent relationship between AWP and providers' acquisition costs[100] or had no expectations of it at all.[101]

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[95] *Ibid*, Appendix II; also, "…the Red Book does not represent its AWP as a measure of the physician's acquisition cost for drugs…".

[96] 1997 OIG Report, p. ii. See, also, Hartman Declaration of Sept. 3, 2004, Attachment D: fn. 10.

[97] Hartman Deposition, pp. 806–807, 923.

[98] Letter from Nancy-Ann Min DeParle to Representative Fortney Pete Stark, January 26, 1998, HHC001-0363–366 at HHC001-363.

[99] Shalala, Donna E., Secretary, Department of Health and Human Services, *Report to Congress: The Average Wholesale Price for Drugs Covered Under Medicare*, 1999, HHC902-0801–18 ("Shalala Report to Congress, 1999") at HHC902-0802–9.

[100] See Deposition of Joe Spahn (Senior health care consultant, Anthem BCBS), November 30, 2004 ("Spahn Deposition"), pp. 20, 97–98 (no particular expectation) and Hartman Deposition, pp. 760–769; and Deposition of Mike Beaderstadt (Director of Provider Relations, John Deere Health Plan), September 17, 2004 ("Beaderstadt Deposition"), pp. 72–73 (no "consistent" relationship).

[101] See Killion Deposition (BCBSMA), pp. 138–139; Deposition of J. Russell Hailey (Chief Pharmacy Officer and Vice President of Pharmaceutical Services, Coventry Health Care), August 4, 2004

2. Plaintiffs allege that each payor formed the same "spread" expectation for each drug, contrary to results of surveys they relied upon

69. Plaintiffs allege that each payor developed a similar range of expectations regarding the "spread" (Dr. Hartman's so-called "market expectations"), and that payors did so in part by relying upon overall averages from particular government surveys and reports.[102] One of the sources cited by Dr. Hartman as corroborating his view—MedPAC—actually found that payors reported using different reimbursement formulae (in particular, discounts) for different categories of drugs, such as chemotherapy, immunizations, and vaccines.[103] Health plan deponents in this matter have also acknowledged that providers' margins may vary across drugs.[104]

70. Note that Dr. Hartman's contention that his sources of information regarding "spreads" corroborate one another[105] is most certainly false. If he had reported the full range of "spreads" reflected in each of these reports, the ranges would be much wider and would not be in agreement with his hand-picked figures for single-source drugs.[106]

3. Payors understood that "spreads" were larger for multi-source drugs, and thus would not expect single-source drugs to serve as "yardsticks" for "spreads"

("Hailey Deposition"), pp. 6, 151–152; and Deposition of Gary Owens (Vice President of medical management and policy at Independence Blue Cross), July 22, 2005 ("Owens Deposition"), pp. 6, 162.

[102] Hartman Declaration of Dec. 16, 2004, ¶¶ 15 (i), 51.

[103] MedPAC, *Report to Congress: Variation and Innovation in Medicare*, June 2003 ("2003 MedPAC Report"), p. 166. This report presents the findings of a survey of approximately 33 health plans performed for MedPAC; see MedPAC, *Health Plan Payment for Physician-Administered Drugs*, A study conducted by Dyckman & Associates, August 2003, No. 03-5, pp. 1 and 3.

[104] Spahn Deposition (Anthem BCBS), pp. 58–59; Deposition of Dan Dragalin (Executive Vice President in charge of the network, Multiplan), September 17, 2004, pp. 9, 99–100.

[105] Hartman Liability Report, ¶ 22.

[106] See section IV.A.

71. A cornerstone of Plaintiffs' theory is that payors formed expectations of the "spread" from available information, and single-source brand name drugs serve as a reasonable "yardstick" for this information.[107] This implies that payors did not have a different expectation of "spreads" for single-source and multi-source drugs, and did not update their expectations when a drug encountered therapeutic or generic competition.

72. Several health plan deponents in this matter have contradicted Plaintiffs' theory. Harvard Pilgrim Health Care, a large health maintenance organization in Massachusetts, purchased brand name drugs from manufacturers at a price of 2 percent to 50 percent off WAC, and generic drugs for 50 percent to 80 percent off WAC.[108] BCBSMA, CIGNA, and Independence Blue Cross, for example, understood that increased price competition causes a reduction in the prices of generic drugs.[109]

73. CMS, and other government agencies that routinely study the Medicare and Medicaid programs, have acknowledged the differences in acquisition costs between single-source and multi-source drugs. For example, a 1997 OIG report cited by Dr. Hartman clearly recognized the difference, finding "average discounts of 18.30 percent below AWP and 42.45 percent below AWP, respectively" for brand name and generic drugs.[110] In a report for CMS, Stephen Schondelmeyer explained that generic drugs generally have larger (and more variable) "spreads" than branded drugs, generally causing the difference between AWP and acquisition costs to be higher for generic than branded drugs.[111]

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[107] Hartman Liability Report, ¶ 22 (a).

[108] Kenney Deposition (Harvard Pilgrim Health Care), pp. 12–13.

[109] Killion Deposition (BCBS MA), pp. 120, 126–129; Deposition of Jill S. Herbold (Assistant Vice President Practitioner Reimbursement, CIGNA), January 14, 2005 ("Herbold Deposition"), pp. 6, 36–37, 86; Kenney Deposition (Harvard Pilgrim Health Care), pp. 12–13; Owens Deposition (Independence BC), p. 136.

[110] OIG, *Medicaid Pharmacy: Actual Acquisition Cost of Brand Name Rx Drug Products*, A-06-00-00023, August 10, 2001, p. 1. See Hartman Declaration of Sept. 3, 2004, Attachment D: ¶ 21.

[111] Schondelmeyer, Stephen W. and Marion V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates, Inc., August 30, 2004, p. 18; see, also, p. 7 ("Most experts

74. Lastly, payors clearly understood that the entry of generic competitors results in price competition that generally reduces the total cost of health care. Many payors have implemented differential dispensing fees[112] and patient co-payment provisions that encourage the use of generic prescription drugs precisely for this reason. It is simply not credible to assume that payors have forgotten the lesson that competition lowers prices when setting reimbursement rates for physician-administered drugs.

4. Payors focus on the total payments to providers, not reimbursement for each drug individually as Plaintiffs' assume, creating variation in "spreads" across drugs

75. Dr. Hartman fails to recognize that the *total* payment is of greater consequence to providers than the division between drug and service components. Medicare policymakers are aware of physicians' concern over the total reimbursement they receive, because only if the total payment is sufficient would physicians be able to cover the costs of the drug, drug administration, and other related practice expenses. For example, CMS and Congress openly discussed cross-subsidization of drug administration fees in revising chemotherapy drug reimbursement rates under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA") (and earlier). Officials were concerned that if they cut reimbursement too far, physicians would cease to serve Medicare patients.[113]

76. In fact, Medicare Part B reimbursement rate reductions have in some instances made it financially impractical for physicians to provide PADs in their offices, forcing patients to seek treatment in hospitals where the costs of care are higher. Two prominent examples are chemotherapy under Medicare's Part B in the late

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agree that AWP, or even the typical discounts to AWP, exceed actual acquisition costs for both pharmacies and physicians. This is particularly true for generic drugs"). See, also, Berndt Report, ¶ 47.

[112] See section IV.D.5.

[113] Letter from members of Congress to Donna E. Shalala, Secretary of the Department of Health and Human Services, July 28, 2000, accessible at http://www.asco.org/prof/pp/html/m_0800shalaltr.htm ("Letter from members of Congress to Shalala, 2000"), p. 1.

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1980s,[114] and intravenous immunoglobulin ("IVIG") under the Medicare Modernization Act's shift from AWP to ASP-based reimbursement.[115]

77. Another factor that caused "spreads" on Medicare Part B drugs to vary during the class period was inconsistency in Medicare carriers' setting of reimbursement rates for J-codes. As a result, reimbursement rates differed by 10 percent or more across Medicare carriers for the same drug for some of the most costly physician-administered drugs.[116] This variation in actual spreads is the result of Medicare policy and carriers' practices, not the behavior of drug manufacturers;[117] in any case, Dr. Hartman fails to grapple with it because he uses published AWPs instead of actual reimbursement rates.

78. Dr. Hartman completely fails to recognize that in negotiating reimbursement rates with a physician practice, insurers are ultimately concerned about the *total* costs of including the practice in its network, since that is what affects the premiums it would have to charge purchasers of its insurance plans. Health plan deponents in this matter have testified regarding their practice of negotiating with providers over the total reimbursement reflected in a fee schedule rather than negotiating each item individually.[118] Because providers' abilities to secure discounts (and thus their

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[114] Dougherty, Elizabeth and Dawn Hagin, "Market Memo: Move Quickly, but Cautiously in Outpatient Cancer Care," *Health Care Strategic Management*, Vol. 7, No. 2, February 1989 ("Dougherty and Hagin, 1989"), p. 18.

[115] "CMS Responds to IVIG Availability Concerns with Add-on Payments for Outpatient Use," *Specialty Pharmacy News*, Vol. 2, No. 12, December 2005, pp. 1–3 ("2005 CMS IVIG Article") at 1–2.

[116] OIG, *Medicare Reimbursement of Prescription Drugs*, OEI-03-00-00310, January 2001 ("2001 OIG Report"), pp. 8–9, Appendix C.

[117] The variation arose because a HCPCS code (J-code) could correspond to anywhere from one to ten NDC codes, which could represent one or more chemical compounds (or different forms, strengths, or packaging), and each carrier could choose different NDCs in developing an "AWP" (i.e., the lowest, median, etc.) to use in determining the J-code reimbursement rate. In addition, carriers updated their AWP calculations at different time intervals. To address this problem, on January 1, 2003, CMS implemented the Single Drug Pricer (SDP) program under which CMS centrally develops AWPs and then distributes them to carriers. CMS chose Palmetto GBA to determine AWPs for the program. The SDP was expected to save the Medicare program $50 million annually. See 2003 MedPAC Report, pp. 154, 160.

[118] Deposition of Susan Johnson (Manager, Medical Policy Support unit, Aetna), March 16, 2005 ("Johnson Deposition"), pp. 6, 101–102; Spahn Deposition (Anthem BCBS), pp. 57–59, 107–110;

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acquisition costs) vary across drugs they purchase, it is readily apparent that providers' "spreads" can be expected to vary across drugs.

79. If physicians were to agree to lower reimbursement rates for one line item—such as drugs—they would have to seek higher reimbursement on another item—such as drug administration fees—to cover the same overall practice expenses. Because this process would be time-consuming and would not ensure sufficient total payments to providers, negotiations with private payors are not conducted in this way. A fee schedule for the bundle of all drugs and services is presented,[119] and a physician or his group negotiates for an overall increase (e.g., 2 percent, 5 percent, 10 percent) on all items in the fee schedule if they find the contract to be unacceptable.[120]

80. Contracting for a bundle of services is likely to minimize transactions costs for insurance companies. Providers are partly responsible for controlling costs such as drug acquisition costs, whereby they may select the appropriate treatments while keeping in mind the total costs of care. It may be easier for the insurer to evaluate the total cost for the bundle of services—for example, by examining the average historical cost of treating patients with a particular disease across many physicians—than to estimate precisely each element. Of course, by contracting for the bundle the insurer also avoids spending resources on micro-managing costs that may be better handled by the provider. Each provider has an incentive to control the costs of care because the insurer can stop contracting with the provider if the quality of service is poor[121] or costs too much.[122]

Owens Deposition (Independence BC), pp. 31–32 (experiences at Delaware Valley HMO), 37–40 (experiences at IBC).

[119] Payors sometimes carve out specific high-cost items to be handled separately, although these items also influence the total payments to providers.

[120] Owens Deposition (Independence BC), pp. 31–32, 37–40.

[121] "Plans have cancelled contracts with physicians who have not met preset [quality of care] standards. Additionally, when periodic reviews by state and/or federal agencies have uncovered quality deficiencies, they have withdrawn approval for physician participation in managed care contracts."

5. Many payors have no ASP expectation, and would not change drug reimbursement if they had more precise knowledge of "spreads"

81. A cornerstone of Plaintiffs' liability theory is that payors needed to know the relationship between providers' acquisition costs and AWP in order to determine reimbursement rates, and that gaining additional information on the topic would cause them to change their reimbursement rates. Notwithstanding the plentiful information available to payors, payors generally do not use information on providers' acquisition costs in setting reimbursement rates. Therefore, Plaintiffs' assumption is invalid for two reasons.

82. First, Plaintiffs' assumption that buyers need to know sellers' costs is simply incorrect as a matter of economics. The Federal Trade Commission ("FTC") has concluded that buyers do not need information on the sellers' cost structures to make efficient purchasing decisions in the overwhelming majority of markets.[123]

83. Second, Plaintiffs' assumptions are wrong for both Medicare and private payors. The public debate surrounding various Medicare reforms confirmed that Congress did not intend to reimburse Part B providers at acquisition costs.[124] Even though Medicare adopted a regulation setting reimbursement at the lower of AWP and EAC (as established by surveys), the surveys were never conducted and the EAC

Shalowitz, Joel I., "Reimbursement Trends in Clinical Oncology: Payment and Quality Issues," *Cancer Investigation*, Vol. 7, No. 3, 1989, pp. 277–282 at 281.

[122] Short, Ashley C. et al., "Provider Network Instability: Implications for Choice, Costs and Continuity of Care," Center for Studying Health System Change, *Issue Brief No. 39*, June 2001.

[123] "In the overwhelming majority of markets, however, consumers have limited or no information about the cost structure of those with whom they do business. More importantly, in general, consumers do not need such information to make efficient purchasing decisions. Instead, consumers make purchasing decisions based on the price and value of goods and services, without regard to a vendor's costs of production." Federal Trade Commission ("FTC"), Letter from the FTC to Assembly Member Greg Aghazarian, regarding California Assembly Bill No. 1960, September 7, 2004 ("FTC Letter to California Assemblyman, 2004"), p. 8.

[124] See the introduction by Senator John Ashcroft of bill S. 3003 (Cancer Care Preservation Act) in the Congressional Record for the 106th Congress, Senate, September 5, 2000, S8019–S8023 ("2000 Ashcroft Statement to the Senate"), at S8022.

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part of the regulation was never implemented.[125] The Administration determined the EAC surveys to be burdensome, unfeasible, and unlikely to be statistically valid.[126] When the Clinton Administration proposed legislation in 1997 to change the reimbursement rate to actual acquisition cost, Congress rejected that proposal.[127] Congress, CMS, and other government agencies understood that Part B drug reimbursement cross-subsidized other inadequately reimbursed (or unreimbursed) services and practice expenses.[128] Due to the implementation of ASP + 6 percent pricing under the MMA, Medicare Part B drug reimbursement rates were reduced but drug administration rates were increased.[129] Congress and CMS continue to study this issue.

84. Under the MMA, drug manufacturers were required to begin submitting quarterly average sale price ("ASP") data to CMS beginning April 30, 2004.[130] CMS would certainly be able to determine the "spread" on every Medicare Part B drug using these ASPs, although Dr. Hartman continues to assess liability throughout 2004 and

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[125] Hartman Deposition, pp. 879–894, 914–919, and Hartman Deposition Ex. 38, 39, 41.

[126] "However, given the wide range of drugs used in different amounts at different frequencies by different types of physicians in different geographic areas of the country, we would have to survey virtually all physicians in order to get a statistically valid estimate of acquisition costs. Because that would have been burdensome and unfeasible, the Administration therefore determined that it would rely instead of the average wholesale price." See Letter from Donna Shalala to Tom Bliley, Chairman, Commerce Committee, House of Representatives, May 31, 2000, HHC001-0359–62 ("Shalala Letter to Bliley, 2000") at HHC001-0359.

[127] Letter from the Deputy Director, Medicare Contract Management, to Medicare Fiscal Intermediaries and Carriers regarding Pricing for Medicare-Covered Drugs, September 14, 2000, AWP041-0943–AWP041-0946 ("DeParle Letter to Carriers, 2000"), at AWP041-0945. A version of the letter addressed to Congress was reproduced in a publication for Medicare Part B providers in Maine, Massachusetts, New Hampshire, and Vermont by the National Heritage Insurance Company of Hingham, Massachusetts; see Health Care Financing Administration, *Medicare B Resource*, National Heritage Insurance Company, October/November 2000, pp. 17–18, accessible at http://www.medicarenhic.com/news/provider_news/ne_mbr_archive/MedB_HR.pdf ("2000 NHIC Part B Newsletter").

[128] CMS, Competitive Acquisition Program Interim Final Rule (CMS-1325-IFC), June 27, 2003; Letter from Glenn M. Hackbarth, Chairman of MedPAC, to Thomas Scully, Administrator of CMS, October 4, 2002, p. 5.

[129] Johnson, Kjel, "Medicare Reimbursement will Affect Specialty Payouts; MMA Pays Less for Drugs, but More for Administering Them," *Managed Healthcare Executive*, July 1, 2004.

[130] 69 Fed. Reg. 17935 (April 6, 2004).

later. CMS makes the ASPs publicly available, so private payors would also be able to observe these "spreads."

85. Health plan deponents in this matter have directly contradicted Plaintiffs' assumption that payors base reimbursement rates on expectations regarding either acquisition costs or "spreads,"[131] and plans indicated they would not change reimbursement methods if they had more information about the relationship between acquisition cost and AWP.[132] For this reason, Dr. Hartman's expectations theory is simply not credible.

D. Competition is expected to generate variation in price concessions and "move market share," which are not fraudulent

86. Plaintiffs assume that large variations in price concessions (and "spreads") are fraudulent and that efforts by manufacturers to "move market share" are suspicious and motivated by a desire to deceive payors. These assumptions reflect fundamental misunderstandings of the nature of competition.[133] In a perversion of economic principles, these assumptions imply that the harder manufacturers compete with one another, the more likely they are to be found "liable" by Dr. Hartman because price competition causes spreads to increase.[134]

1. Competition generates price concessions, which vary by market conditions and the characteristics of the buyer

87. When several products can be used to treat the same underlying condition, buyers can choose among therapies based on the clinical profile of the drug and its price.

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[131] See section III.C.1.

[132] Spahn Deposition (Anthem BCBS), pp. 93–95; Mulrey Deposition (BCBSMA), pp. 65–73, 129–130; Hailey Deposition (Coventry), pp. 151–152;. Some payors confirmed a similar policy for self-administered drugs; see Deposition of William Fleming (Vice President of pharmacy and clinical integration, Humana), January 11, 2005 ("Fleming Deposition"), p. 18–19, 41–42; Deposition of James Messinger (Vice President of Managed Care, ULLICO), October 22, 2004 ("Messinger Deposition"), pp. 20, 64–65.

[133] For a discussion of the nature of pricing and competition in the pharmaceutical industry, see Congressional Budget Office ("CBO"), *How Increased Competition from Generic Drugs has Affected Prices and Returns in the Pharmaceutical Industry*, July 1998 ("1998 CBO Report").

[134] I discuss movements in benchmark prices in sections V and VI.

Naturally, when more than one drug is effective for a condition, price may be one of the product's characteristics that influences the buying patterns of customers (physicians).[135, 136]

88. In this environment, price concessions are a natural outgrowth of competition. A customer can either expressly negotiate for a lower price by threatening to move his or her business to the rival drug or simply do so when offered a lower price. Customers who behave in this way will extract price concessions from manufacturers of competing drugs.

89. Note, however, that not all patients or physicians may find the drugs to be good substitutes. Some physicians or patients have brand loyalty to a particular drug (for example, they care a great deal about a particular side effect). Since some loyal customers would not switch to the competitor's drug when offered a lower price, they often pay higher prices. The result of these differing tastes and ability to substitute across drugs means we would see a variety of discounts in the market.

90. Variation in discounts is also generated by differences across physicians in terms of the administrative costs resulting from such factors as expedited purchase and delivery requirements or placement of large orders. Variation in discounts also arises from differences in the cost to the manufacturer of *not* serving a particular customer at a particular time, for example, when a rival gains more market share or a plant does not operate at capacity. The process by which manufacturers use discounting to charge different prices to different customers is an important element of price competition.[137]

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[135] See Hartman Liability Report, Attachment F: p. 7 (Smithkline Kytril): "I am requesting a 4.5% increase for all forms of Kytril…using weight based dosing in which the average does should be approximately .7mg Kytril would maintain a price advantage. Kytril IV currently does not have a price advantage compared to Anzemet, however based on Kytril's more favourable safety profile and well established efficacy in preventing chemotherapy induced nausea and vomiting, a higher price for a better product is justified."

[136] I discuss pharmaceutical price concessions more fully in Bell, Gregory K. and Scott Morton, Fiona, Tutorial Submission of the Track One Defendants, "An Orientation to the Acquisition of and Reimbursement for Prescription Drugs," December 3, 2004, section 11.F.

[137] 1998 CBO Report, pp. 23–24.

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2. Variation in price concessions causes variation in spreads

91. A benchmark price applies to all customers and changes slowly, while price concessions typically vary over time and across customers. Therefore, the difference between the two, or the spread, must vary. The spread varies across customers, because each customer is able to negotiate a different discount from the manufacturer. The spread varies across drugs, because each drug faces a different level of competition. The spread varies as new technologies are introduced and competition intensifies over the product lifecycle due to entry of therapeutic and generic competitors, new indications for existing drugs, and other factors.

3. Price concessions are normally confidential

92. It is common in many industries for negotiated price concessions to remain confidential, especially when discounts are individually negotiated with buyers. In competition between pharmaceutical products—such as branded therapeutic substitutes—price concessions are likely to occur only if kept confidential.[138] Even health insurance companies generally attempt to maintain the confidentiality of the prices and discounts they negotiate with providers,[139] and the lowest prices reported to the government for the Medicaid program are confidential.[140] Because the transactions of any two buyers often differ in one or more ways and some buyers may not be entitled to the same price terms, their prices would not be the same; thus, public disclosure of discounts may lead to confusion and misunderstandings.

4. Competition is expected to "move market share"

93. It is a fundamental principle in economics that customers "move" market share in response to financial incentives such as lower prices; this is normal economic behavior. More than that, it is crucial to reducing healthcare costs. Imagine what would happen if a manufacturer raised its price and did not lose sales. If that

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[138] Berndt Report, ¶ 166.

[139] For example, Independence Blue Cross considers its reimbursement rates to be propriety trade secrets; see Owens Deposition (Independence BC), pp. 81–83.

[140] The "best price" and average manufacturer price ("AMP") are kept confidential by CMS.

manufacturer were economically rational, it would raise price again and again. The prospect of losing sales (and market share) as prices exceed customers' willingness to pay limits price levels and keeps healthcare costs from being any higher than they otherwise would be. Similarly, when a manufacturer lowers price and gains sales, this is standard price competition.

5. However, Plaintiffs' theory treats vigorous competition as fraudulent

94. Although competition is expected to involve price concessions—which may be quite large—and movements in market share, Plaintiffs nonetheless assume that this normal economic behavior is fraudulent. Plaintiffs assume any action that generates large "spreads," whether due to vigorous price competition or to benchmark price movement, to be fraudulent.

95. Plaintiffs allege that because drug discounts and rebates are paid to providers and do not directly accrue to end payors and patients, they generate inappropriate profits and cause end payors and patients to overpay for drugs.[141] However, allowing intermediaries in the pharmaceutical distribution chain to retain some of the savings associated with price concessions is important in stimulating price competition.[142]

96. As Professor Berndt has stated, for self-administered drugs, payors have allowed providers to have margins on drugs in order to encourage the use of generic drugs.[143] Professor Berndt confirmed that "one widely understood reason third-party payors have long been willing to allow pharmacies to enjoy considerable 'spread' on their generic drugs is that whenever a generic version of a drug is dispensed instead of its brand version, the third-party payor saves a substantial

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[141] Third Amended Complaint, ¶¶ 3, 177–178, 183, 187–194.

[142] Danzon, Patricia, Gail Wilensky, and Kathleen Means, "Alternative Strategies for Medicare Payment—Part B and Beyond," *American Journal of Managed Care*, Vol. 11, No. 3, March 2005, pp. 173–180 at 175. For example, as the FTC notes that the financial incentive of being able to retain part of any cost-reducing effort is an important incentive that drives the PBM to seek lower purchase prices; see FTC Letter to California Assemblyman, 2004, p. 2.

[143] See, for example, Owens Deposition (Independence BC), pp. 182–183.

amount of money."[144] The same principle may apply to physician-administered drugs.[145] More broadly, this example illustrates the principle that allowing some of the savings to remain with a party in the distribution chain can be a purposeful choice on the part of payors to achieve an objective. In a later section, I explain how public and private payors are not only aware of the spread but make use of it to achieve their objectives.

97. When manufacturers or others in the distribution chain compete for a physician's business for generic or branded PADs, they typically offer price concessions. Allowing dispensers to capture some of the benefit of lower acquisition cost creates an incentive for them to be price-sensitive, which ultimately leads manufacturers to compete by reducing prices. A similar incentive is created for any intermediaries in the physician-administered drug distribution chain, such as specialty pharmacies. Ultimately, the final payor benefits from lower costs in the supply chain, and this is why the payor designs reimbursement schemes to include incentives for other parties to seek price concessions.

98. Note also that allowing providers to retain some of the savings from price concessions is more likely to create downward pressure on future reimbursement rates—whether through negotiations with private payors or in public policymaking for Medicare—than if providers received none of the savings from negotiating larger price concessions from manufacturers.

E. No reasonable payor would expect uniform price concessions or "spreads"

1. Payors acknowledge that "spreads" vary across drugs, across buyers, and after therapeutic competition

99. As I discuss above, publicly available reports have documented that "spreads" vary across drugs, and it has also been acknowledged by health plan deponents in this

[144] Berndt Report, ¶ 52.

[145] Payors who reimburse for PADs under a pharmacy benefit program may provide these types of incentives to physicians.

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matter[146] and by Medicare policymakers.[147] Payors have also acknowledged the variation in acquisition costs of different buyers[148] and the variation in price concessions that results from therapeutic and generic competition. For these reasons alone, no reasonable payor would expect providers to obtain uniform price concessions or spreads across different drugs.

2. Many payors are aware of variation in "spreads" across specific drugs from their experiences with, and available information about, SADs and PADs

100. As I discuss later, many private payors became involved in drug purchasing from manufacturers through vertical integration into such operations as specialty pharmacies, staff model HMOs, mail order pharmacies, and PBMs.[149] These experiences provided private payors with plentiful information about "spreads" on SADs and PADs.

101. The Congress, the CMS, and the OIG were aware of the variation in "spreads" across specific drugs from their studies of SADs and PADs under the Medicaid program. I do not believe it to be credible to assume they would have forgotten this lesson when turning their attention to the Medicare Part B program.

3. Medicare's repeated studies of acquisition costs would be unnecessary if "spreads" were predictable

102. In its role as a large public payor under the Medicare program, the government is interested in maintaining adequate participation by providers while monitoring the cost of the program. For this reason, Medicare policymakers have routinely studied market participants and the functioning of the industry, including the costs of providers and Medicare Part B reimbursements. Of course, if Medicare policymakers believed there to be a predictable relationship between ASP and

[146] See section III.A, III.C.

[147] 1992 OIG Report.

[148] See, for example, 1992 OIG Report, Appendix III; Cannon Deposition (IHC Health Plans), pp. 26, 57–58.

[149] See section IV.B.1.

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AWP, there would be no need to expend substantial efforts to repeatedly study acquisition costs and price concessions.[150]

4. No reasonable purchaser would expect the same range of discounts for every product for all time

103. While Plaintiffs view the growth in the difference between acquisition costs and reimbursement rates as a purposeful attempt by manufacturers to increase the "spread" above "market expectations," it is unreasonable to expect a market system with many participants to remain static for decades—with or without fraud. Prices and margins would generally be expected to change, for example, due to changes in the competitive landscape (such as consolidation of firms in the industry, entry of new firms, or new products), changes in regulation, or the evolution of operating procedures.

104. In particular, there have been several developments in the pharmaceutical industry that have slowly altered the observed "spread" over the class period. For example, consolidation in the wholesale industry led to economies of scale,[151] so that wholesalers no longer need a 25 percent margin to cover their costs. The development of formularies by PBMs and HMOs intensified price competition among manufacturers to get placement on a formulary. As part of formulary implementation, insurers may send information to physicians about the formulary or use "counter-detailing" representatives, which again intensified price competition as this enabled the insurers to become more adept at moving prescriptions between therapeutic substitutes.[152, 153]

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[150] Dr. Hartman has acknowledged these efforts by payors to inform themselves. See Hartman Declaration of Dec. 16, 2004, fn. 13.

[151] IMS Health, *Pharma Pricing USA: A Comprehensive Review of Pharmaceutical Pricing in the Mid-1990s*, 1995, pp. 103–105.

[152] See, for example, Dietert, Stephanie, "Pharmaceutical Plans Strive to Improve Prescription Benefits," *San Antonio Business Journal*, Vol. 10, No. 36, September 20, 1996.

[153] Information technology allowed for formularies and drug tiers to be applied at the individual patient level and changed with ease. Additionally, adoption of information technology by pharmacies and insurance companies allowed for adding or dropping of pharmacies from an insurer's network easily and inexpensively, which improved an insurer's negotiating position vis-à-vis the pharmacy.

105. One of the major business innovations of the last 20 years has been the stimulation of price competition among branded therapeutic substitutes by large buyers such as HMOs, insurance companies, and the VA. Buyers' efforts to learn how to "move market share" are procompetitive, rather than a problem as alleged by Plaintiffs, because this ability brings transaction prices down although it has the side effect of increasing the spread.

IV. Payors were Not Deceived by Large "Spreads"

106. Without any support from the record on payors in this matter,[154] Plaintiffs' allege that payors were first deceived and then harmed by increases in the "spread," and they characterize payors as helpless to learn about "spreads" or mitigate any resulting increases in reimbursement costs.[155] Further, they do not consider the possibility that payors who continue to use an AWP-based reimbursement system during the class period made a conscious choice after evaluation of the merits of alternatives.

107. If payors had the means to inform themselves or counteract the alleged cost increases to them, then clearly this would mitigate harm from the alleged fraud if not the alleged fraud itself. In assuming that payors were only informed by publicly-available government reports and would not otherwise inform themselves or take actions to counter the alleged "spread," Plaintiffs are making an inference that is not supported by economic logic, industry knowledge, or even their own expert.[156]

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[154] Dr. Hartman did not rely on payors' deposition testimony, documents, or data produced in this matter in his expectations theory or liability "yardstick;" see Hartman Deposition, pp. 686–689, 706–710, 795–796. Dr. Rosenthal did not rely on conversations with class members, deposition testimony, payors' documents, or conversations with payors in forming her opinions; see Rosenthal Deposition, pp. 31–33, 36–37, 52–54, 127–128.

[155] Hartman Declaration of Dec. 16, 2004, ¶¶ 3 (c), 15 (f), 47; Rosenthal Liability Report, ¶ 26.

[156] Dr. Hartman has acknowledged payors' efforts to inform themselves through studies. See Hartman Declaration of Dec. 16, 2004, ¶ 15(f)(i), fn. 13.

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108. In this section, I discuss several independent reasons why payors were not deceived by large spreads. If even one of these reasons holds, then there was either no fraud or payors could have easily avoided being deceived.

A. Payors had access to plentiful information on prices and spreads

109. One of the cornerstones of Plaintiffs' theory is that payors were unaware of the size of the spreads between AWP and providers' acquisition cost. As noted above,[157] there were numerous government reports and investigations throughout the class period that gave Medicare and private payors indications of the range of discounts on PAD prices in relation to WAC or AWP, for both generic and branded drugs. Dr. Hartman acknowledges that payors made use of such publicly available reports[158] and conducted their own studies;[159] this has been confirmed by Dr. Rosenthal,[160] individual private payors,[161] and Medicare.[162] Dr. Hartman describes some of these sources as informing "market expectations" of "spreads," however these reports provide examples of discounts (from which Dr. Hartman calculated "spreads") substantially larger and more variable than Dr. Hartman's "liability threshold." Note that Dr. Hartman misrepresents what is reported in the government reports: most of the reports present discounts off AWP or WAC—which by definition cannot exceed 100 percent—while Dr. Hartman uses the same discounts to calculate "spreads" (or mark-ups), which are sometimes hundreds or thousands of a percent above costs.

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[157] See section III.A.6.

[158] Hartman Declaration of Dec. 16, 2004, ¶ 51. See, also, Hartman Declaration of Sept. 3, 2004, Attachment D: ¶ 24: "It is reasonable to expect that the findings of these reports form some part of the basis for beliefs about the typical "spread" between AWP and actual acquisition costs of providers (physicians) and retail drug stores."

[159] Hartman Declaration of Dec. 16, 2004, ¶ 15(f), fn. 13.

[160] Rosenthal Deposition, pp. 46–47.

[161] See, for example, Beaderstadt Deposition, pp. 15–16, 19–21; Letter from Nancy-Ann DeParle to members of Congress, in 2000 NHIC Part B Newsletter, pp. 17–18.

[162] "We have followed closely the investigations of drug pricing conducted by the DOJ and the Department of Health and Human Services' Inspector General." See DeParle Letter to Carriers, 2000, at AWP041-0945.

110. Nonetheless, examples of such "spreads" calculated from the discounts in government reports include: albuterol sulfate, 116 percent to 180 percent;[163] doxorubicin, 127 percent to 143 percent;[164] doxorubicin HCL, 215 percent to 224 percent;[165] etoposide, 71 percent to 94 percent;[166] and Zofran, 30 percent to 42 percent.[167] Government officials involved with the Medicare program were informed of large "spreads" and so-called "mega-spreads" before and during the Class period. In 1996 HCFA was informed by Ven-A-Care that "Medicare's reimbursement was excessive and in many cases provided profit margins of more than 500% and, in some instances, more than 1000%."[168] Ven-A-Care stated that"[f]or approximately seven years, we have diligently worked in an attempt to inform responsible government officials, including HCFA and others, of the cause and effect that excessive reimbursements for infusion and inhalation drugs are having on our health care delivery system."[169] Also, the Secretary of the Department of Health and Human Services, Donna Shalala, acknowledged in 1999 the 13-year history of OIG reports documenting "spreads."[170] She also described

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[163] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J7620). "Spreads" were calculated as ("Actual Medicare Allowed Amount" – "Actual Average Wholesale Price") / "Actual Average Wholesale Price". The prices in Appendix B are from 1995–1996, a period when Medicare statutes specified reimbursement at the lesser of AWP and EAC (although the EAC provision was never implemented, as I discuss above).

[164] 1992 OIG Report, pp. 2, 5–6, and Appendix III. "Spreads" were calculated as: (1) for page 5, ("AWP" – "Physician Cost") / "Physician Cost"; (2) for Appendix III, "Invoice Costs Expressed as a Percentage Below the AWP" / (1 – "Invoice Costs Expressed as a Percentage Below the AWP").

[165] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J9000, J9010).

[166] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J9181, J9182).

[167] 1997 OIG Report, Appendix B. pp. B-2, B-3 (J2405 – Ondansetron Hydrochloride).

[168] See, for example, the Letter from Zachary Bentley to Dr. Bruce Vladeck, Administrator, Health Care Financing Administration, regarding Excessive Reimbursements for Certain Pharmaceuticals by the Medicare and Medicaid Programs, October 2, 1996, HHC003-0479–84 ("1996 Bentley Letter to HCFA"), at HHC003-0481.

[169] 1996 Bentley Letter to HCFA, HHC003-0480.

[170] "For the past 13 years, the Office of Inspector General (OIG) has issued a series of reports that consistently show a finding that the Medicare program overpays for the drugs and biologicals it covers. This is because most drugs can be obtained at a much lower cost than the AWP....The OIG's most recent studies are 'Excessive Medicare Payments for Prescription Drugs' (OEI-03-97-00290, December 1997) and 'Comparing Drug Reimbursement: Medicare and Department of Veterans Affairs' (OEI-03-97-293, November 1998). On average, for the 22 drugs in the OIG study, Medicare payment at the AWP allowed a markup of 41 percent above the drugs' wholesale catalog price advertised to the

how in 1997 "the HHS Inspector General found payments based on average wholesale price data to be 11 to 900 percent greater than the prices available to the physician community."[171]

111. The differences between AWP and providers' acquisition costs were also publicized in general circulation newspapers and magazines.[172, 173, 174, 175] Examples of such "spreads" include: doxorubicin, 254 percent;[176] and etoposide, 318 percent.[177] Dr. Hartman's assumption that payors were unaware of the size of "spreads" was explicitly contradicted by a group of approximately 32 health plans (representing 45 million covered lives) who participated in a survey by MedPAC, on which Plaintiffs' rely:[178] "Plan respondents were aware that physicians typically purchased drugs at prices well below AWP and that the payment methods resulted in additional profits for physicians," "some plans used varying percentages of AWP for different categories of drugs," and "[a]bout one-half of the plans considering

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physicians and suppliers who bill Medicare"; see Shalala Report to Congress, 1999, at HHC902-0802–03.

[171] Shalala Letter to Bliley, 2000, at HHC001-0360.

[172] See, for example, Sanger, Elizabeth, "No Rx for Plans; Drug Plans Draw Pharmacists' Ire," *Newsday*, February 24, 1989, p. 47: "insurers say the average wholesale price isn't the price they pay for drugs. Depending on the medicine, the acquisition price can be as much as 50 percent less than the average wholesale price, [Richard] Kaplan [President of the eastern division of CIGNA Health Plans] says. Moreover, there can be several average prices."

[173] "Pharmacists Face Big Losses Under Proposal, Official Says," *Arkansas Democrat-Gazette* (Little Rock, AR), March 23, 1989: "Bill Mc Cutcheon of Dallas, deputy regional administrator of the Health Care Finance Administration, said numerous studies and 'open admission by the people who publish those prices' has shown that the average wholesale price 'doesn't represent the actual cost' to pharmacies 'by any stretch of the imagination.'"

[174] Colburn, Don, "Drug Prices: What's Up?," *Washington Post*, December 15, 1992, p. Z8: citing "deep discounts that large-volume buyers such as chain stores, hospital groups and HMOs can bargain for."

[175] Hooked on Drugs, 1996, p. 15: "For many drugs, especially the growing number coming off patent and going generic, the drug providers actually pay wholesale prices that are 60%–90% below the so-called average wholesale price, or AWP, used in reimbursement claims." These discounts off AWP correspond to spreads of 150 percent to 900 percent. The article lists examples of injectables and IV solutions, some of which are Subject Drugs in this litigation.

[176] Hooked on Drugs, 1996. "Spreads" are calculated as ("'95 AWP" – "Wholesale Price") / "Wholesale Price."

[177] Hooked on Drugs, 1996.

[178] See, for example, Hartman Liability Report, ¶¶ 22 (c), 27.